

May 11, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

RE: Comments to the Interim Final Rule Concerning Changes to the Medicare Appeals Process, CMS-4064-IFC

Dear Sir or Madam:

On behalf of the Power Mobility Coalition (PMC), a national association for manufacturers, suppliers, and beneficiaries of motorized scooters and power wheelchairs, we are submitting comments in response to the changes to the Medicare Appeals Procedures that has been published as an interim final rule in 70 Fed. Reg. 11,420 -11,499 (Tuesday, March 8, 2005). The interim final rule is entitled "*Medicare Program: Changes to the Medicare Claims Appeals Procedures.*"

The PMC supports reforms to the Medicare Appeals Procedures that streamlines the process, provides statutorily finite timelines, respects the rights of beneficiaries and suppliers, and alleviates unnecessary administrative burdens on petitioners while maintaining balance, fairness, and justice in the system. To this end, the PMC has the following comments concerning the recently released interim final rule:

USE OF PATIENTS' MEDICAL RECORDS

Section 405.968(a) of the interim final rule states, in part, the following:

If the initial determination involves a finding on whether an item or services is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's [Qualified Independent Contractor] reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

This regulation does not define "medical record" nor does it address specific items and services that require physician completion of a Certificate of Medical Necessity ("CMN").

Recommendation: The agency should clarify that the CMN is a medical record and that Congress established the CMN to demonstrate medical necessity. In fact, the CMN is defined by Congress as a “form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member.”¹ The CMNs were developed by CMS and the medical community and have been approved and reapproved by the OMB.

When the CMNs were developed and approved by the OMB subject to formal public notice and comment, CMS stated the following in its 1996 PRA submission:

For the CMNs which remain, the DMERC medical directors have determined the specific information needed to make a medical necessity determination. This information requires the application of medical judgment that can only be provided by a physician or other clinician who is familiar with the condition of the beneficiary.²

The content of the motorized wheelchair CMN has remained the same since initial approval in 1996.

The Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) reiterated the same theme in a fraud alert in 1999, entitled “*Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services,*” in which it stated:

The Medicare program only pays for health care services that are medically necessary. In determining what services are medically necessary, Medicare primarily relies on the professional judgment of the beneficiary’s treating physician, since he or she knows the patient’s history and makes critical decisions, such as admitting the patient to the hospital; ordering tests, drugs, and treatments; and determining the length of treatment. In other words, the physician has the key role in determining the medical need for and utilization of, many health care services, including those furnished and billed by other providers and suppliers. Congress has conditioned payment for many Medicare items and services on a certification signed by a physician attesting that the item or service is medically necessary. For example, physicians are routinely required to certify to the medical necessity for any service for which they submit bills to the Medicare program.

¹ Section 1834(j)(2) of the Social Security Act passed as part of the Social Security Act amendments of 1994.

² HCFA PRA Submission, *Durable Medical Equipment Regional Carrier, Certificates of Medical Necessity*, 5 (November 6, 1996).

Physicians are also involved in attesting to medical necessity when ordering services, or supplies that must be billed and provided by an independent supplier or provider. Medicare requires physicians to certify to the medical necessity for many of these items and services through prescriptions, orders, or, in certain specific circumstances, Certificates of Medical Necessity (CMNS). These documentation requirements substantiate that the physician has reviewed the patient's condition and has determined that services or supplies are medically necessary.³

In March 2004, CMS Administrator Dr. Mark McClellan confirmed to the United States Senate that the CMN is the appropriate documentation to show that the beneficiary's need for the equipment is supportable:

As a condition of coverage, CMS does require that the beneficiary's need for a wheelchair or power wheelchair is supportable. In fact, all claims for power wheelchairs must include a Certificate of Medical Necessity (CMN) which "certifies the need for the device and that it is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body part."⁴

INITIAL DETERMINATIONS

The interim rule, pursuant to Section 405.922, requires that a contractor issue initial determinations within 30 days for clean claims.⁵ Failure to comply with the 30 day period will result in an interest payment to the individual awaiting such determination.

For non clean claims, the contractor must issue an initial determination within 45 days of receipt. The proposed rule does not provide for any interest payment should the determination extend beyond the 45 day time period.

Recommendation: We propose that the term "non clean" claim be defined so that Medicare participants will know when a claim will no longer be considered "clean." If a claim is paid at the QIC or ALJ level (or higher), such claims should be considered "clean" as a mistake was made by the carrier and interest should accrue from the date of the original denial. This would assure fairness and provide incentives to expedite claim determinations.

³ 64 Fed. Reg. 1813-1816 (Jan. 12, 1999) (emphasis added).

⁴ Answers for the record to questions submitted by Senator John Kerry from the Senate Finance Committee Hearing on the nomination of Mark B. McClellan, to be Administrator of the Center for Medicare & Medicaid Services (March 8, 2004).

⁵ The term "clean claim" is defined in Section 1842 of the Social Security Act as "a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment to prevent timely payments from being made on the claim."

REDETERMINATION

The proposed rule, pursuant to Section 405.966, requires that a party, “when filing a request for reconsideration” must “present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination... Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.”⁶

Recommendation: The requirement that parties submit all evidence prior to the redetermination decision places suppliers in a difficult position. We thus recommend that information obtained during the process is allowed to be submitted at any level. To deny the introduction of such evidence at any stage of the review process will have the impact of short-circuiting justice and denying a fair finding of fact if all relevant evidence is not allowed to be considered.

Parties must be afforded the opportunity to present new evidence at all levels of the appeals process. This is the only way to ensure true justice for all Medicare participants.

QUALIFIED INDEPENDENT CONTRACTOR LEVEL

On the Record Hearing

In order to meet statutory guidelines concerning time limits for appeals before Qualified Independent Contractors ("QIC"), CMS is proposing that all QIC appeals be "on the record." This would mean that Medicare participants would not have the opportunity to have a QIC determination in person or via telephone.

Recommendation: Medicare participants should have an opportunity to have a QIC hearing in person or via telephone. The opportunity to appear before a hearing officer or a QIC (in person or via telephone) is an important due process right for the provider/supplier and/or the beneficiary. Often times, Medicare beneficiaries participate in hearings with the supplier/provider and the opportunity of the hearing officer to witness the condition of the beneficiary is extremely important to the process. Further, Medicare participants should be allowed to present their case and address in person specific questions that might arise during the hearing.

Independence and Training of QIC's

The implementing legislation defines a QIC as “an entity or organization that is independent of any organization under contract with the Secretary.” The legislation further provides that a QIC would have sufficient training and expertise in medical science and legal matters. Pursuant to Section 405.968 of the interim rule, QIC’s “who

⁶ 70 Fed. Reg. 11481.

conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare Program.”⁷

Recommendation: The interim rule must set forth in greater detail the independence of the QIC and spell out in greater detail the specific legal expertise of the QIC. This being the case, we would propose that each QIC have a law degree or specific legal training (as well as a medical background) so that a complete understanding of the Social Security Act and the implementing regulations become part of any decision. Further, the proposed rule must clarify that any QIC (as well as anyone providing assistance to a QIC) be completely independent of the carrier and agency involved in this matter. Absent such language, we would contend that the interim rule does not comply with the intent of the implementing statute.

Further, will the QIC supercede the judgment of the patient’s treating physician? If so, what would be the circumstances that justify such an override and when will Medicare participants not be able to rely on the treating physicians’ expertise and paperwork? In the case of certain DME items, a supplier/beneficiary relies on the treating physician’s certification contained in the CMN. In these cases, the appeals rule should outline the circumstances that would justify an override of the treating physician’s completion of Medicare paperwork.

REOPENINGS

Section 405.980 of the interim rule provides that a contractor may reopen a claim(s) within 4 years from the date of the initial determination for good cause as defined in 405.986. Pursuant to 405.986, good cause may be established when (1) there is new and material evidence that was not available or known at the time of the determination or decision and may result in a different conclusion or (2) the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.⁸

Recommendation: The reopening of claims should be consistent with the concept of finality and fairness to the beneficiary, provider/supplier and the agency. Often times, the carrier seeks information that was readily available at the time of the original claim determination) and still claims that this meets the regulatory good cause standard. The carrier makes this claim even though it was at all times in complete control of the entire review process. It appears the carrier is arguing that its own internal system for review does not permit it to timely complete reviews or enable it to comply with federal regulations developed by CMS.

We think the current good cause standard should be enforced to ensure fairness and finality for those that participate in the Medicare program.

⁷ 70 Fed. Reg. 11481.

⁸ 70 Fed. Reg. 11484.

ESCALATION

Time Frames

The proposed rule affords Medicare participants an opportunity to “escalate” to the next level of appeal should a decision not be rendered within the time frames outlined in the proposed rule.

Recommendation: We would recommend that time frames remain intact should a participant “escalate” to the next level. A participant should not lose his/her rights to an expedited hearing simply because a decision was not rendered at a lower level of appeal within the timeframe set forth in law. If decisions are not made within 45 days of a hearing, the Medicare participant should have an automatic right to escalate to the next level.

INDEPENDENCE AND FAIRNESS OF ALJs MUST BE ESTABLISHED AND MAINTAINED

Steps must be taken to ensure that ALJs maintain their independence as their oversight is transferred from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS). Specifically, the PMC is concerned that HHS training of ALJs will focus on more restrictive CMS policy or CMS program memoranda as opposed to federal statutes, regulations and case law.

Safeguards must be put in place to ensure that CMS cannot, through training or agency culture, attempt to influence the decisional independence of ALJs handling Medicare claims. At a minimum, HHS should ensure that:

- firewalls are put in place to ensure independence;
- procedures should be implemented for reporting and overseeing ALJ operations; and
- standards should be developed against which the independence of ALJs is measured.

We appreciate your time and consideration of these issues and look forward to working with HHS, CMS, and the power mobility community to address these concerns and ensure a fair and equitable Medicare appeals process.

Sincerely,

Eric W. Sokol
PMC Director

Stephen M. Azia
PMC Counsel